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5/26/98

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

May 15, 1998

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98 - 29

Carl Ross
President, Greenco Industries, Inc.
c/o Kittlesen, Barry & Ross
P.O. Box 710
Monroe, Wisconsin 53566

Dear Mr. Ross:

During a recent inspection of Greenco Industries' drug manufacturing facility located at 1601 Fourth Avenue West, Monroe, WI, our investigator documented numerous serious deviations from Good Manufacturing Practice regulations (GMP) for Finished Pharmaceuticals, Title 21, Code of Federal Regulations (21 CFR), Parts 210 and 211. Articles of drug manufactured in a facility which is not operated in conformance with GMP are adulterated within the meaning of Section 501(a)(2)(B).

Deviations from GMP include:

1. Failure to establish a Master record for fluoridated toothpaste, and failure to maintain production batch records.

2. Failure to establish written Standard Operating Procedures for significant operations.

3. Failure to establish or maintain labeling controls.

4. Failure to establish criteria for, or to perform testing on, incoming drug product or packaging components.

In addition, the fluoride toothpaste packaged at this site is subject to all requirements of the Over-the-Counter monograph, "Anticaries Drug Products for OTC Use," described in 21 CFR Part 355.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Good Manufacturing Practice regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction.

You should notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

At the conclusion of our inspection on March 26, 1998, form FDA-483, Inspectional Observations, was issued to Mr. Don Templin. Your written response to this office should address each of the items cited on this list.

To assist you in preparing your response I have enclosed a copy of the March 26, 1998 form FDA-483, the OTC monograph, "Anticaries Drug Products for OTC Use (21 CFR 355), and "GMP for Finished Pharmaceuticals (21 CFR 210 & 211).

You may direct your reply to Compliance Officer Lawrence R. Murphy at the address indicated on the letterhead.

Sincerely,

James A. Rahto
Director
Minneapolis District

LRM/ccl

Enclosures: 21 CFR 355
21 CFR 210 & 211
FDA-483, 3/26/98

xc: Donald D. Templin
Chief Executive Officer
Greenco Industries, Inc.
1601 Fourth Avenue West
Monroe, WI 53566